ACEVISION

OCT 3 ' 2007

510(k) Summary
(per 21 CFR 807.92)

K070296

I. Applicant

ACE VISION GROUP
247 N. Westmonte Road
Altamonte Springs, FL 32714

Contact Person: Tim Elliott, VP Operations
Tel: (216) 632-1988
Fax: (440) 815-2262
Email: telliott@acevisiongroup.com

Date Prepared: August 17, 2007

II. Device Name

Proprietary Name:	VisioLite® Ophthalmic Er:YAG Laser System
Common/ Usual Name:	Laser instrument, surgical, powered
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation Number:	878.4810
Product Codes:	GEX
Classification:	2
Classification Panel:	General & Plastic Surgery

III. Predicate Device

The VisioLite® Ophthalmic Er:YAG Laser System is substantially equivalent to the Oculase MD from Biolase Technology Inc and the Laserscope Vela Erbium:YAG laser system. The Oculase MD was cleared by the FDA under 510(k) K052354 and the Vela Erbium:YAG laser system was cleared by the FDA under 510(k) K971843

IV. Intended Use of the Device

The VisioLite® is indicated for the ophthalmic soft tissue surrounding the eye and orbit.

V. Description of the Device

The VisioLite® Ophthalmic Er:YAG Laser System creates a laser beam with a wavelength of 2940nm, which is highly absorbed by water, collagen and hydroxy apatite and therefore causes rapid vaporization, or ablation, in both hard and soft biological tissues. Because the absorption is highly efficient, tissue removal is very precise with virtually no collateral thermal damage.

The VisioLite® Ophthalmic Er:YAG Laser System is equivalent in design to the Delight laser System from Hoya ConBio.

VI. Summary of the Technical Characteristics

Type of Laser	Er:YAG
Laser Beam Wavelength	2940 nm (invisible, mid-infrared)
Energy Output	Up to 350 mJ
Type of Operation	Pulsed Only, Pulse Width < 300 μsec
Angle of Laser Beam Divergence at Tip	230 mrad
Class of Laser Products	Class IV

VII. Safety & Effectiveness

There are no substantial differences between the VisioLite® Ophthalmic Er:YAG Laser System defined in this 510(k) submission and the predicate devices.

The VisioLite® Ophthalmic Er:YAG Laser System included electrical safety testing , laser safety testing and electromagnetic compatibility testing.

The VisioLite® Ophthalmic Er:YAG Laser System meets the applicable requirements of CFR 1040.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ace Vision Group
% Emergo Group Inc.
Mr. Ian P. Gordon
Senior Vice President
1705 South Capital of Texas Highway
Suite 500
Austin, Texas 78746

OCT 3 ˇ 2007

Re: K070296
Trade/Device Name: VisioLite® Ophthalmic Dr: YAG Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: September 18, 2007
Received: September 19, 2007

Dear Mr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

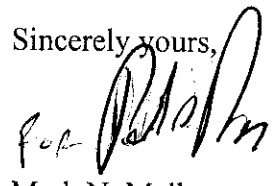
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the

quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4. Indication for Use Statement

510(k) Number (if known): K070296

Device Name: VisioLite® Ophthalmic Er:YAG Laser System

Indications for Use:

The VisioLite® is indicated for the ophthalmic soft tissue surrounding the eye and orbit.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070296